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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/836,548	04/18/2001	John A. Drewe	1735.0450001/RWE/BEC	6789
26111	7590	02/06/2004	EXAMINER: COLEMAN, BRENDA LIBBY	
STERNE, KESSLER, GOLDSTEIN & FOX PLLC 1100 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005			ART UNIT 1624	

DATE MAILED: 02/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/836,548

Applicant(s)

DREWE ET AL.

Examiner

Brenda L. Coleman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14, 22-40, 47-88 and 90-92 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-9, 11-14, 22-37, 39, 40 and 48-53 is/are allowed.
- 6) ☒ Claim(s) 10, 38, 47, 54-88 and 90-92 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date. _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-14, 22-40, 47-88 and 90-92 are pending in the application.

This action is in response to applicant's amendment filed October 29, 2003.

Claims 89 and 97 have been canceled and claims 1-14, 22-25, 27-40, 47-54, 57, 60-74, 76-84 and 86 have been amended.

Response to Arguments

Applicant's amendments filed October 29, 2003 have been fully considered with the following effect:

1. The applicant's amendments and arguments are sufficient to overcome the improper Markush group of claim 49 maintained in the last office action, which is hereby **withdrawn**.
2. The applicant's amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, first paragraph rejection of claims 1-14, 22-40, 47-93 and 97 labeled paragraph 2 of the last office action, which is hereby **withdrawn**.
3. With regards to the 35 U.S.C. § 112, first paragraph rejection of claims 54-88 and 97 maintained in the last office action, the applicant's arguments have been fully considered, however they were not found persuasive. The applicants stated that the examples disclosed in the present specification involving three types of cancer cells and five different compounds of the claimed invention indicate that the compounds are effective in inducing apoptosis in cancer cells. The applicants have tested one compound, i.e. example 70, which is embraced by the instant invention. The applicant's

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also stated that "it is now known that cancer cells are, *inter alia*, generally characterized not only by a loss of cell cycle control but also by resistance to apoptosis". Raymond W. Ruddon, *Biochemistry of Cancer* provided by the applicants, states that "it would be thearapeutically advantageous to tip the balance in favor of apoptosis over mitosis in tumors, it that could be done". Vaux et al., *Cell*, Vol. 96, pages 245-254 cited in the text of Raymond indicates that the "genetic and, more recently, biochemical studies have revealed much of the effector mechanisms of apoptosis, but the details of most of the signaling pathways that can trigger apoptosis are poorly understood".

As stated in the last office action, the MPEP, 2164.08 "[t]he Federal Circuit has repeatedly held that the specification must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. In re Wright, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). Nevertheless, not everything necessary to practice the invention need be disclosed. In fact, what is well-known is best omitted. In re Buchner, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991). All that is necessary is that one skilled in the art be able to practice the claimed invention, given the level of knowledge and skill in the art. Further the scope of enablement must only bear a reasonable correlation to the scope of the claims. See, e.g., In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). As concerns the breadth of a claim relevant to enablement, the only relevant concern should be whether the scope of enablement provided to one skilled in the art by the disclosure is commensurate with the scope of protection sought by the claims. In re Moore, 439 F.2d 1232, 1236, 169 USPQ 236, 239 (CCPA 1971). See also *Plant Genetic Sys., N.V. v.*

DeKalb Genetics Corp., 315 F.3d 1335, 1339, 65 USPQ2d 1452, 1455 (Fed. Cir. 2003) (alleged a pioneer status of invention irrelevant to enablement determination)."

Claims 54-88 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. For reasons of record and stated above.

4. With regards to the 35 U.S.C. § 112, first paragraph rejection of claims 57-65, 89-93 and 97 maintained in the last office action, the applicant's arguments have been fully considered but are not found persuasive. The applicant's stated that examples of particular diseases and its symptoms the invention is used to treat can be found in the specification, *inter alia*, at page 35, line 15, through page 36, line 5 as well as page 38, line 24 through page 41, line 30, etc. However, as stated in the previous office action the scope of the method claims are not adequately enabled for the treatment of each and everyone of the asserted diseases and/or disorders in the specification, nor is there any testing to indicate that the compounds of the instant invention are effective in the treatment of the asserted diseases and/or disorders. As stated above in paragraph 3, Raymond W. Ruddon, Biochemistry of Cancer provided by the applicants, states that "it would be thearapeutically advantageous to tip the balance in favor of apoptosis over mitosis in tumors, it that could be done". Vaux et al., Cell, Vol. 96, pages 245-254 cited in the text of Raymond indicates that the "genetic and, more recently, biochemical studies have revealed much of the effector mechanisms of apoptosis, but the details of most of the signaling pathways that can trigger apoptosis are poorly understood". With

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out the knowledge of the signaling pathways that can trigger apoptosis, it is difficult to determine what diseases and/or disorders are affected by the induction of apoptosis.

Claims 57-65 and 90-92 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. For reasons of record and stated above.

5. The applicant's amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, second paragraph labeled paragraph 5e) and 5ag) maintained in the last office action, which are hereby **withdrawn**.

6. The applicant's amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, first paragraph rejection of claim 97 labeled paragraph 6 of the last office action, which is hereby **withdrawn**.

7. The applicant's amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, second paragraph rejection of claims 12, 34, 53, 60, 62, 69, 71 and 81 labeled paragraph 8 of the last office action, which are hereby **withdrawn**.

In view of the amendment dated October 29, 2003, the following new grounds of rejection and/or reinstated rejections apply:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 47, 54-56, 64, 65, 73-75 and 83-88 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The compound 4-hydroxy-3-[7-(4-chloro-2-methoxy-phenyl)-2,3,6,7-tetrahydro-[1,4]thiazepin-5-yl]-6-methyl-pyran-2-one is not described in the specification.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

9. Claims 10, 38, 55, 63, 72, 82 and 85 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a) Claim 10 is vague and indefinite in that it is not known what is meant by the 2,3,6,7-tetrahydro-1,4]thiazepin-5-yl which is missing an open bracket.

b) Claim 38 recites the limitation "methoxy" in the nomenclature of the species. There is insufficient antecedent basis for this limitation in the claim.

c) Claims 55 and 85 are vague and indefinite in that it is not known what is meant by a cancer chemotherapeutic agent, which reads on a plethora of possible compounds.

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d) Claim 63 recites the limitation "2-chloro" in the nomenclature of the last species on page 43. There is insufficient antecedent basis for this limitation in the claim.

e) Claim 72 recites the limitation "2-chloro" in the nomenclature of the second species on page 59. There is insufficient antecedent basis for this limitation in the claim.

f) Claim 82 recites the limitation "2-chloro" in the nomenclature of the seventh species on page 74. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

10. Claims 47, 54-56, 64, 65, 73-75 and 83-88 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility. There is no statement of utility for the species 4-hydroxy-3-[7-(4-chloro-2-methoxy-phenyl)-2,3,6,7-tetrahydro-[1,4]thiazepin-5-yl]-6-methyl-pyran-2-one which is not described in the specification.

Allowable Subject Matter

Claims 1-9, 11-14, 22-37, 39, 40 and 48-53 are allowed. None of the prior art of record nor a search in the pertinent art area teaches the compounds of the instant invention as claimed herein.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda L. Coleman whose telephone number is 571-272-0665. The examiner can normally be reached on 8:30-5:00 Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 571-272-0674. If you are unable to reach Dr. Shah within a 24 hour period, please contact James O. Wilson, Acting -SPE of 1624 at 571-272-0661.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Brenda Coleman
Primary Examiner Art Unit 1624
February 5, 2004